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PATENT

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Appl. No.: 10/614,255  
Applicant: Mary Wilkes Eubanks  
Filed: July 3, 2003  
Art Unit: 1638  
Examiner: Keith O. Robinson  
Title: METHOD AND MATERIALS FOR INTROGRESSION OF  
NOVEL GENETIC VARIATION IN MAIZE

Mail Stop Appeal Brief – Patents  
Commissioner for Patents  
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Alexandria, VA 22313-1450

**REPLY BRIEF UNDER 37 CFR § 41.41**

This Reply Brief is filed in response to an Examiner's Answer mailed June 11, 2009.

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## **2. Statement of Additional Facts.**

The unique recombinant DNA fragments of the present invention are not found in the *Zea* parent (*i.e.*, teosinte such as *Zea diploperennis*), *Tripsacum* sp. parent (*i.e.*, *Tripsacum dactyloides*), or maize parent (*i.e.*, *Zea mays* L.) {p. 1 of US Patent App. No. 10/614,255}.

Mutations are rare, and most are deleterious {p. 3, lines 8-19, of *id.*} and are typically at random or by chance {p. 20, lines 20-22, of *id.*}. Mutation rates vary and range from 1 in 1,000 ( $10^3$ ) to 1 in 1,000,000 ( $10^6$ ) {p. 20, lines 11-14, of *id.*}.

The *Tripsacum*-teosinte hybrids (*i.e.*, intergeneric plants) used in making the maize plants of the present application have mutations at 148 out of 176 loci, which is an unprecedented mutation rate {p. 20, lines 16-18, of *id.*} in view of the accepted teachings in the art regarding mutations. Even though the mutations should occur at random or by chance, they are repeatable and stably inherited in crosses and as shown in the present application in backcrosses {p. 20, lines 28-33, of *id.*}. Mutations that carried over into trigeneric plants were expected to be lost or diluted upon backcrossing to maize, but were not {p. 20, lines 28-33, of *id.*}.

Furthermore, the same unique recombinant DNA fragments of the present invention are found in siblings as well as *Zea-Tripsacum* progeny from crosses

between different parents with differing ploidy levels and from different provenances {p. 22, of *id.*}.

This is counterexample to accepted teaching that there is no clustering of mutations and that siblings from the same family never share a common mutant allele {p. 20, lines 22-26, of *id.*}. The finding that same unique recombinant DNA fragments are repeatedly found in siblings of the same parentage and in progeny of distinctly different *Zea* and *Tripsacum* parents {p. 20, lines 26-33, of *id.*} is an unexpected scientific discovery that would not have been predicted by one skilled in the art.

### **3. Arguments.**

On p. 6, lines 1-5, of the Examiner's Answer, the Examiner states that "one of ordinary skill in the art would have [a] reasonable expectation of success based on the success of Eubanks (1994) in crossing Tripsacorn with maize." In addition, on p. 7, lines 17-22, of the Examiner's Answer, the Examiner states that "one of ordinary skill in the art would have [a] reasonable expectation of success based on the success of Eubanks (1992) in crossing Tripsacorn with corn." The response is that it was unexpected and unpredictable that such a large number of recombinant DNA fragments from trigeneric plants would be stably inherited in successive generations by the backcrosses rather than lost in the backcrosses.

None of the references cited in the Office Action discloses such backcrosses, and the Examiner has not provided any reference that bridges the gaps between the claimed invention and the cited references by showing that one of skill in the art could have reasonably predicted the unexpected retention of such a large number of recombinant DNA fragments following the backcrosses. Moreover, Appellant, who is the same person as the inventor/author of the cited references, did not contemplate or perform such backcrosses until later, as she also believed that the recombinant DNA fragments of intergeneric or trigeneric plants would be lost in the backcrosses.

One of skill in the art cannot reasonably predict the results of the backcrosses based solely on the generation of intergeneric and trigeneric plants as shown in Eubanks (1992) and Eubanks (1994). In crosses between two intergeneric plants or two trigeneric plants, the genetic background of the two plants is presumably identical; therefore, one of skill in the art expects that the cross would reinforce the genetic identity of such plants. In contrast, backcrossing is a cross of an intergeneric or trigeneric plant with one of the parental strains to achieve offspring with a genetic identity that is closer to that of the parent. The claimed invention defies conventional plant genetics in that the offspring of the backcross retain a far greater genetic identity to the intergeneric or trigeneric plant than would be predicted. This finding is not only novel over the art, but non-obvious as well.

On the bottom of p. 8 through the middle of p. 9 of the Examiner's Answer, the Examiner states that "the fact that appellant is the author/inventor of the cited reference is irrelevant because the cited references were published more than one year before the effective filing date of the instant application." The response is that Appellant raised this issue to highlight to the Examiner that Appellant is the most qualified, given the facts of this case, to comment on what was obvious or not in the art at the time between the cited references and the filing date of the present application.

As noted above, Appellant did not contemplate or perform such backcrosses at the time of Eubanks (1992) or Eubanks (1994) because she believed, as the art did, that most of the recombinant DNA fragments would be lost in the backcrosses. It was not until the backcrosses were actually performed that Appellant discovered that the resulting maize plants unexpectedly retained the recombinant DNA fragments. One of skill in the art would have predicted that the backcrosses would reinforce the parental genetic background, especially given that mutations are disfavored. Surprisingly, the present application shows that upon the backcrosses, the maize plant comprises the recombinant DNA fragments. This finding is not only novel over the art, but non-obvious as well.

### Conclusion

Appellant maintains that the Examiner has not demonstrated a *prima facie* case of obviousness in view of the cited references. The combination of references pertains at best to creating maize-*Tripsacum* hybrids, but fails to contemplate or disclose the claimed backcrossed plants and recombinant DNA fragments. For the reasons set forth herein and in Appellant's Appeal Brief, Appellant requests

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reversal of the rejections of the claims, allowance of the claims and passing of the application to issuance.



Respectfully submitted,

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I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Mail Stop Appeal Brief-Patents, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on July 30, 2009.

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